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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,898	10/26/2006	Ellen Jessouroun	NIH275.001NP2	9576
45311 7590 12/01/2008 KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER ARCHIE, NINA				
ART UNIT		PAPER NUMBER		
1645				
MAIL DATE		DELIVERY MODE		
12/01/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,898

Applicant(s)

JESSOUROUN ET AL.

Examiner

Nina A. Archie

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2008 has been entered.

Withdrawal of Rejection

2. The rejection of claims 1-14 under 35 U.S.C. 103(a) has been withdrawn in view of applicants declaration.

New Grounds of Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Application No. 10/566,899.

In the instant case, the claims are drawn to method for preparing a conjugate vaccine, the method comprising: reacting a polysaccharide with an oxidizing agent, whereby a solution of an aldehyde-activated polysaccharide is obtained; reacting a protein with hydrazine dichloride at an acidic pH, whereby a solution of a hydrazine-activated protein is obtained; reacting the aldehyde-activated polysaccharide with the hydrazine- activated protein at a pH of from about 5 to about 7 in the presence of sodium cyanoborohydride, whereby a conjugate is obtained; and neutralizing unreacted aldehyde groups with acidic acid dihydrazide, whereby a conjugate vaccine capable of stimulating an immune response is obtained.

Claims 1-12 of U.S. Application 10/566,899Patent No. 6,610,293 method for preparing a conjugate vaccine, the method comprising: reacting a polysaccharide with an oxidizing agent, whereby a solution of an aldehyde-activated polysaccharide is obtained; reacting a protein with hydrazine dichloride at an acidic pH, whereby a solution of a hydrazine-activated protein is obtained; reacting the aldehyde-activated polysaccharide with the hydrazine- activated protein at a pH of from about 5 to about 7 in the presence of sodium cyanoborohydride, whereby a conjugate is obtained; and neutralizing unreacted aldehyde groups with acidic acid dihydrazide, whereby a conjugate vaccine capable of stimulating an immune response is obtained.

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Application No. 10/566,898 recites the method as set forth supra. The species of the method anticipate the genus claims of any method.

Thus, claims 1-20 encompassing the method in the present application are obvious over claims 1-12 of Application No. 10/566,899.

Furthermore for two or More Copending Applications

If two (or more) pending applications are filed, in each of which a rejection of one claimed invention over the other on the ground of provisional nonstatutory double patenting (ODP) is proper, the provisional ODP rejection will be made in each application. If the >provisional< ODP rejection is the only rejection remaining in the earlier-filed of the two pending applications, (but the later-filed application is rejectable on other grounds), the examiner should then withdraw the provisional ODP rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the provisional ODP rejection is the only rejection remaining in the later-filed application, (while the earlier-filed application is rejectable on other grounds), a terminal disclaimer must be required in the later-filed application, before the >provisional< ODP rejection can be withdrawn. If the provisional ODP rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw the provisional ODP rejection in the earlier-filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the provisional ODP rejection can be withdrawn and the application be permitted to issue. The phrase "earlier-filed" is to be interpreted as follows: (A) Where there is no benefit claim in the two applications, the "earlier-filed" application is the one having the earlier actual filing date; (B) Where at least one of the two applications is entitled to the benefit of a U.S. nonprovisional application under 35 U.S.C. 120, 121, or 365(c), the "earlier-filed" application is the one having the earlier effective U.S. filing date, when taking into account each of the benefit claims under 35 U.S.C. 120, 121, and 365(c). Entitlement to the benefit claims under 35 U.S.C. 120, 121 and 365(c) assumes appropriate support in the relied-upon earlier-filed application's disclosure (and any intermediate application(s)) for the conflicting claims of the two (or more) applications; (C) A 35 U.S.C. 119(e) benefit is NOT taken into account in determining which is the "earlier-filed" application; (D) A foreign priority claim under 35 U.S.C. 119(a) is NOT taken into account in determining which is the "earlier-filed" application. If both applications are filed on the same day, the provisional ODP rejection made in each of the applications should be maintained until applicant overcomes the rejections by either filing a reply showing that the claims subject to the

provisional ODP rejections are patentably distinct or filing a terminal disclaimer in each of the pending applications.

Status of the Claims

5. No claims allowed.
Claims 1-20 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/N. A. A./

Examiner, Art Unit 1645

Nina A Archie
Examiner
GAU 1645
REM 3B31

/Mark Navarro/

Primary Examiner, Art Unit 1645